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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,326	09/18/2003	Earl O. Bergersen	BER-P-03-052	6248
29013	7590	05/22/2007		
PATENTS+TMS, P.C. 2849 W. ARMITAGE AVE. CHICAGO, IL 60647			EXAMINER O'CONNOR, CARY E	
			ART UNIT 3732	PAPER NUMBER
			MAIL DATE 05/22/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/665,326

Applicant(s)

BERGERSEN, EARL O.

Examiner

Cary E. O'Connor

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-123 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-123 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-123 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. In the first paragraph of each of the independent claim, applicant positively recites part of a human, i.e. "dental appliance **worn in a mouth of a user**". Thus claims 1-123 include a human within their scope and are non-statutory. A claim directed to or including within its scope a human is not considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. In re Wakefield, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 48 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not disclose how the hinge with the holes and projections therethrough is removable from the bases. The only

embodiment disclosed that includes holes through the hinges and projections of the bases in the holes is the embodiment where the appliance is molded around the hinge (see page 45, lines 8-11). It is unclear how the hinge can be removable.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 47, 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Bergersen (4,898,535). Bergersen '535 shows a dental appliance comprising a U-shaped upper base, a U-shaped lower base, each having a flat occlusal surface wherein the occlusal surface contacts the teeth when the base is worn, and a hinge 44 which, since the bases are molded around the hinges, are inherently inserted into slots (formed during the molding process) in the bases. During the molding process, projections are inherently formed through the holes. The U-shaped bases have a slot or socket formed therein wherein the last molar is inserted into the slot and wherein the first and second ends extend beyond the last molar (see figure 7) particularly if all the molars haven't erupted. As to claim 49, note that the hinge may be made of metal (column 3, lines 30-31) which is inherently harder than the material of the bases. As to claim 47, note the holes formed in the hinge (figure 5). As to claim 52, note the labial shield 38. Regarding claims 53-55, note the cavities in the upper and lower bases

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(formed by the curvature of the lingual flanges) to receive the tongue. As to claims 21, 112, the cavity would inherently move the tongue outward when it comes into contact with the lingual flanges.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 50 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bergersen (4,898,535) in view of Bergersen (5,876,199). The appliance of Bergersen '535 does not include holes in the base. Bergersen '199 shows a dental appliance comprising an upper base, a lower base, and a hinge. The appliance includes holes in the base 402 to increase air intake while wearing the device. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the appliance of Bergersen '535 with holes in the base, to increase air intake while wearing the device.

Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bergersen (4,898,535) in view of Bergersen (5,645,420). The labial shield of Bergersen '535 does not extend past the upper teeth. Bergersen '420 shows a dental appliance comprising an upper base, a lower base, and a hinge. The appliance includes a labial

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shield 30 that extend past the upper teeth to provide a constant distallizing guidance against the pre-maxilla. It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the labial shield of Bergersen '535 so that it extends upwardly past the upper teeth, as taught by Bergersen '420, in order to provide a constant distallizing guidance against the pre-maxilla.

### ***Claim Objections***

Claim 30 is objected to because of the following informalities: In claim 30, line 10, "prevent" should be changed to --prevented--. Appropriate correction is required.

### ***Response to Arguments***


Applicant's arguments with respect to claims 1-123 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cary E. O'Connor whose telephone number is 571-272-4715. The examiner can normally be reached on M-Th 7:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cris Rodriguez can be reached on 571-2724964. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Cary E. O'Connor  
Primary Examiner  
Art Unit 3732

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